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Attorney Docket Number	39994A

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
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  - Reply Brief

Remarks

No Oral Hearing is requested. Although no fee is believed due by submission of this paper, authorization is hereby made to charge any fees due or outstanding, or credit any overpayment, to Deposit Account No. 18-2220 (Order No. 39994A).

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Roylance, Abrams, Berdo and Goodman, L.L.P.		
Signature	Stacey J. Longanecker		
Printed name	Stacey J. Longanecker		
Date	October 6, 2008	Reg. No.	33,952

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	:	Attorney Docket No. 39994A
Glenn P. Vonk et al.	:	Confirmation No. 5157
Serial No.: 09/881,041	:	Group Art Unit: 3626
Filed: June 15, 2001	:	Examiner: Thomas, Joseph
For: A HEALTH OUTCOMES AND DISEASE MANAGEMENT NETWORK AND RELATED METHOD FOR PROVIDING IMPROVED PATIENT CARE	:	

REPLY BRIEF UNDER 37 CFR § 41.41(a)(1)

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Sir:

For the appeal to the Board of Patent Appeals and Interferences from the decision rejecting claims 1-25 as set forth in the final Office Action of August 22, 2007, Appellant submits the following reply brief in response to the Examiner's Answer of August 6, 2008 in accordance with 37 C.F.R. § 41.41(a)(1).

I. Status of Claims

There is no dispute as to the status of the claims as set forth in the April 22, 2008 Appeal Brief, and noted as being correct in the August 6, 2008 Examiner's Answer.

II. Grounds of Rejection on Appeal

There is no dispute as to the grounds of rejection on appeal as set forth in the April 22, 2008 Appeal Brief, and noted as being correct in the August 6, 2008 Examiner's Answer.

III. Reply to Examiner's Answer of August 6, 2008

A. Initial Comments paragraphs

In the Examiner's Answer, the Examiner states that the following quoted statement from Appellant's Appeal Brief is not found in independent claims 1, 8, or 15 and so Appellant's arguments that the references do not show this recitation were considered outside the Examiner's Answer:

> *"each of these claims recites that the accumulated health-related data is revised or updated based on patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of health related conditions"*

Appellant's disagree and reproduce claims 1, 8 and 15 below with the relevant language highlighted.

> *1. A system for monitoring health-related conditions of patients, comprising:*
>
> *a plurality of remote monitoring stations, each being configured to receive patient health-related data pertaining to a respective patient; and*
>
> *a computer network comprising a* ***database containing accumulated health-related data*** *pertaining to health-related conditions and treatments that reveals population trends and outcomes and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network* ***configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions****;*
>
> *said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of*

questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools;

said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient in response to said progress determination.

8. A method for monitoring health-related conditions of patients, comprising:

obtaining patient health-related data pertaining to patients at a plurality of remote monitoring stations, each being configured to receive respective said patient health-related data from a respective said patient;

***storing accumulated health-related data** pertaining to health-related conditions and treatments that reveals population trends and outcomes in a database of a computer network;*

receiving at said computer network said patient health-related data from said remote monitoring stations pertaining to respective patients;

controlling said computer network to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data;

*controlling said computer network to **revise said accumulated health-related data based on said patient health-related data;***

generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs;

receiving economic data relating to protocols used in said treatment programs;

aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care; and

determining** from said aggregated data **recommendations for improving the treatment programs.

15. A method for managing health-related conditions of patients, comprising:

assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients;

collecting healthcare data by using each said healthcare manager to collect respective patient health-related data for each respective patient in their said group of patients;

determining whether each respective patient is suitable for participation in a treatment program;

controlling a computer network to receive said health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each said patient in a database, ***said database further including accumulated data*** *pertaining to health-related conditions and treatments that reveals population trends and outcomes;*

coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment program for each respective patient in their said group of patients based on said patient health-related data pertaining to that respective patient and said accumulated data; and

updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions;

wherein the determining step comprises the steps of

obtaining agreement from a respective patient to participate in a treatment program; and

receiving approval from a payer who will pay for the treatment program;

wherein the controlling step comprises the steps of

receiving health-related data for a respective patient comprising assessment of the patient's medical, psychosocial and environmental conditions;

receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient.

B. Claims 1-7 are Not Obvious under 35 U.S.C. § 103(a) Over Ballantyne in view of Joao and further in view of Summerell

1. Regarding the claim language in claim 1 that recites a computer network comprising "a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes...," the Examiner states that the language "...reveals

population trends and outcomes..." has no patentable weight because it is considered an intended used of the data. Appellants disagree. Data that reveals something is an affirmatively recited characteristic of that data that should be given patentable weight. Appellants did not recite data for determining trends but rather data that reveals trends; therefore, the claim language in question in claim 1 should not be considered an intended use.

2. Regarding the following recitation in claim 1:

> *"said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions;"*

the Examiner contends that the recitation of "for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions" is considered the intended use of the computer. This language qualifies the preceding "said accumulated health-related data" in that the accumulated health-related data is used to identify improvements in standards of care and medical practices, as claimed. Since the accumulated health-related data reveals population trends and outcomes, it can be used in this manner, which represents an advantage of the present invention. If this use of accumulated health-related data is not recited sufficiently clearly, it may be useful to revise "for identification of improvements" to read "and using said accumulated health-related data to identify improvements."

Nevertheless, Ballantyne does not disclose said accumulated health-related data that reveals population trends and outcomes nor revising it as claimed. Fig. 10B of Ballantyne relied on by the Examiner merely discloses updating a patient's medical record. Ballantyne, however, fails to teach accumulated health-related data that reveals population trends and outcomes, let alone how updating a patient's medical record in Fig. 10B is used to revise accumulated health-related data that reveals population trends and outcomes.

The Examiner's Answer states that claim 8 does not contain the above-quoted limitation; however, claim 8 has the following similar language:

> *"storing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes in a database of a computer network;*
> *receiving at said computer network said patient health-related data from said remote monitoring stations pertaining to respective patients;*
> ...
> *controlling said computer network to revise said accumulated health-related data based on said patient health-related data;*
> ...
> *aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care; and*
> *determining from said aggregated data recommendations for improving the treatment programs."*

Appellants respectfully submit that claim 8 recites that accumulated health-related data pertains to health-related conditions and treatments and reveals population trends and outcomes in a database of a computer network, and patient health-related data pertains to respective patients. The accumulated health-related data comprising population outcomes and generic standards of care is revised based on

patient health-related data, and is also aggregated with patient health-related data and other data as claimed. Recommendations for improving the treatment programs are determined from the aggregated data. Clearly, in claim 8, accumulated health-related data is not the same as the patient health-related data if it is aggregated with it, or even a stored collection of patient health-related data wherein respective patient records can be updated as the Examiner appears to suggest. Ballantyne at most arguably teaches that respective patient medical records can be updated, but is silent regarding accumulated health-related data that pertains to health-related conditions and treatments and reveals population trends and outcomes, or its revision based on patient health-related data, or determining from it recommendations for improving the treatment programs.

Claim 15 recites in part:

> *"controlling a computer network to receive said health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each said patient in a database, said database further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes;*
>
> ...
>
> *updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions;"*

The Examiner's Answer states that it is not clear from claim 15 how the improvements relate to the updating of the data. Appellants submit that identifying improvements occurs with the updated accumulated data, and that this is clear since identifying improvements is recited in the same step of updating said accumulated data and not as a separate step.

The Examiner also points to column 16, lines 50-61 of Ballantyne to purportedly teach the claimed invention. Column 16, lines 50-61 of Ballantyne teach a regional library wherein dedicated services are allocated to specialized medical research fields such as cancer or diabetes. The regional library is accomplished by acquiring relevant information on a specific field from all of the interconnected hospital master libraries, which can include medical data from which patient information has been purged. A software management and data search/sort is provided to assist research oriented users. Thus, Ballantyne discloses that raw specific field data is acquired from all hospital master libraries, and that a tool is needed to search and sort it. Appellants submit, however, that the specific field data of Ballantyne does not constitute stored accumulated data that reveals population trends and outcomes as claimed, nor accumulated data that reveals population trends and outcomes that is updated based on patient health-related data.

3. The Examiner states that Summerell as relied on to purportedly teach the following recitation from claim 1:

> *"said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools;"*

Appellants have argued that Summerell does not render this claimed aspect of the present invention obvious because Summerell does not disclose an electronic self-

management tool that allows a patient to integrate a health care provider's established treatment program, but rather seeks to provide a tool for users to select their own wellness plan without involvement of a heath care provider. In the Examiner's Answer, the Examiner states that there is nothing in the second limitation of claim1 requiring that a health care provider be involved except to provide a treatment program. Appellants submit that such a proposed limitation is not needed to overcome Summerell.

As recited in the first recitation of claim 1, a computer network is configured to "provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data," which provides the antecedent basis for "a selected one of said treatment programs" recited in the second limitation. Appellants submit that Summerell does not render this claimed aspect of the present invention obvious. In Summerell, the patient selects his own wellness plan from a computerized interactive wellness system where wellness options are automatically selected for the user based on user input and not selected by a healthcare provider. Summerell therefore teaches away from a claimed invention wherein a computer network is configured to "provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data," and a remote monitoring stations are configured with electronic self-management tools for receiving from a respective patient said patient health-

related data relating to integration of a selected one of said treatment programs into the patient's lifestyle, as recited in the first recitation of claim 1. As stated in column 5, lines 47-53 and lines 60-62 of Summerell, the wellness measurement and wellness options systems disclosed therein seek to reduce the difficult and time-consuming data collection task of physicians by providing systems that "collect data directly from the patient." Thus, the Examiner's broad interpretation of Summerell is in contradistinction to what the reference actually teaches.

Also, the reliance on column 4, lines 15-19 of Summerell in support of the Examiner's position is also a misinterpretation. The questions to be asked of a doctor mentioned in column 4, lines 15-19 of Summerell refer to questions to ask as a patient "progresses in the personalized wellness program" that is set up as a result of the patient using the system, that is, *after* the system is used by the patient to set up and obtain his/her wellness program. Thus, the health care provider is not involved in the set up or establishment of the program as the Examiner suggests. The physician can merely augment the data entered by the patient into the system with test results (e.g., patient's blood pressure). See column 5, lines 60-67 of Summerell. The claimed invention, by contrast, provides "a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data," per claim 1.

4. The Examiner states the Appellant does not argue whether Joao teaches the fourth limitation of claim 1. Appellants repeat arguments

presented in the Amendment dated June 8, 2007. Joao is silent regarding electronic assessment tools to allow a health care provider to determine whether information relating to a selected treatment program needs to be conveyed to the patient in response to progress determination, as recited in amended claim 1. Joao briefly mentions that the system described therein provides healthcare-related treatment progress reports (see column 4, lines 46-47 of Joao), ensures treatments are performed as prescribed (see column 5, lines 23-24 of Joao), and allows a subsequent provider to re-evaluate a patient's condition and seek additional assistance (see column 5, lines 31-32 of Joao), but none of these references to Joao indicates determining whether information relating to a selected treatment program needs to be conveyed to the patient in response to progress determination.

C. Claims 8-14 Are Not Obvious under 35 U.S.C. § 103(a) over Ballantyne et al and Joao in view of Seare

1. For reasons stated above, Appellants submit the Ballantyne fails to teach or suggest at least the following recitations of claim 8:

> *storing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes in a database of a computer network;*
> *receiving at said computer network said patient health-related data from said remote monitoring stations pertaining to respective patients;*
> ...
> *controlling said computer network to revise said accumulated health-related data based on said patient health-related data;*
> ...
> *aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related*

> *data comprising population outcomes and generic standards of care; and*
>
> *determining from said aggregated data recommendations for improving the treatment programs."*

Further, Joao and Seare do not overcome these deficiencies.

2. The Examiner states in the Examiner's Answer that "the act of storing data, in a broad interpretation, is revising that data" and relies on this interpretation to assert that Ballantyne teaches "controlling said computer network to revise said accumulated health-related data based on said patient health-related data" in claim 8 by citing col. 2, lines 24-63. Appellants disagree with this unreasonable interpretation, and find that the Examiner has not clearly set forth how such an interpretation is being analogized to purportedly teach the specific claim limitations in question. The Examiner appears to be saying that anything stored in Ballantyne constitutes accumulated health-related data, and that anything else stored with that data effectively changes that data, in an effort to show that Ballantyne teaches "controlling said computer network to revise said accumulated health-related data based on said patient health-related data." A database that changes because it receives a new record, however, does not teach or suggest the recited invention.

To establish *prime facie* obviousness, all words in a claim must be considered in judging the patentability of that claim against the prior art. M.P.E.P. 2143.03. Claim 8 recites that patient health-related data pertains to patients, that accumulated health-related data pertains to health-related conditions and treatments and reveals population trends and outcomes, and that accumulated

health-related data is revised based on the patient health-related data, among other limitations. Ballantyne does not discuss how any of the data items listed col. 2, lines 24-63 reveals population trends and outcomes, nor that storing a patient record would change a data item that reveals population trends and outcomes.

3. Regarding the recitation of "controlling said computer network to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data" in claim 8, the Examiner states "tools" are an intended use, that the claim is silent on whom or what creates treatment programs, and that it is the Examiner's position that something other than the claimed method creates the treatment programs "based upon said tools." Appellants disagree. Claim 8 clearly states that electronic treatment establishment tools establish the treatment programs. Appellants do not understand where the Examiner obtained the "based upon" language for his interpretation. Further, recitation of an electronic tool to establish a treatment program precludes an interpretation that it is done manually via an interaction between a physician and a patient as the Examiner appears to suggest.

4. The Examiner noted Appellant's remark that Seare et al does not disclose or suggest aggregating outcomes and generic standards of care with other data, but states that this is not claimed. This is incorrect. Claim 8 recites "aggregating said patient health-related data, said clinical data and said

economic data with said accumulated health-related data comprising population outcomes and generic standards of care." Thus, population outcomes and generic standards of care are recited as aggregated with other types of data such as clinical data and economic data.

5. Regarding the recitation of "generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs" in claim 8, the Examiner states that Appellant's specification is silent regarding what specifically is generated, yet notes the generation of reports. The Examiner cites paragraphs 58 or 83 as examples, but Appellants also respectfully direct attention to additional parts of the specification to exemplify generated clinical data comprising outcomes. First, the broadest reasonable interpretation of the claims must be consistent with the interpretation that those skilled in the art would reach. Outcomes can be results. In the health care art, for example, outcomes could be interpreted by one skilled in the art as outcomes of clinical interventions delivered to patients by health care providers. Paragraph [0078] of the specification states that an outcomes report can be generated to report of a client's progress, and that benchmarking can be done for clinical and economic outcomes. Outcomes analysis (e.g., benchmarking and comparisons), and measured results (e.g., hospitalizations) on which clinical outcomes, for example, can be based, are also discussed in paragraphs [0112]-[0113].

6. The Examiner states that he is confused by the Appellants' argument that, "if Seare et al can provide outcome information from medical billing data that may arguably teach clinical data as claimed, then such outcome data cannot also be relied on to teach population outcome information as claimed." Appellants respectfully assert that the Examiner has improperly relied on the same information in Seare et al to teach two different recited elements, that is, both clinical data and the population outcomes in the accumulated health related data.

The Examiner has deemed the Appellants' arguments "a piecemeal approach." Appellants respectfully submit that a reference such as Seare et al, which has been used in combination with other references as the grounds for rejection, can be properly attacked on an individual basis for failing to teach what it has been purportedly relied on to teach.

7. The Examiner relies on the abstract of Seare et al to purportedly teach the aggregating and determining steps of claim 8. Billing data of a medical provider is used to create a normative utilization profile for that provider. The Examiner states that a collection of individual billing records in Seare et al teaches population outcome as claimed. The Appellants disagree. As recited in claim 8, the recited said accumulated health-related data comprises the population outcomes and is not taught in Seare et al as claimed (e.g., revised based on patient health-related data and pertains to health-related conditions and treatments and reveals population trends and outcomes). Further, even if Seare et

al arguably discloses economic data, it is silent regarding aggregation of clinical data, patient health-related data and the accumulated health related data.

D. Claims 15-21 and 23-25 are Not Obvious under 35 U.S.C. §103(a) over Ballantyne and Joao in view of Russek and further in view of Soll et al

1. Appellants submit that Ballantyne does not teach the controlling or updating steps for reasons stated above in connection with claim 1.

2. The Examiner states that "determining whether each respective patient is suitable for participation in a treatment program" is not defined. Appellants disagree. Claim 15 recites:

> "*wherein the determining step comprises the steps of obtaining agreement from a respective patient to participate in a treatment program; and*
> *receiving approval from a payer who will pay for the treatment program;*"

Paragraph [0058] of Soll et al mentions that "patients initially undergo the computerized CPM interview session and are then evaluated by a physician" but is otherwise silent regarding receiving payer approval as claimed.

3. In claim 15, a healthcare manager is distinguished from a member of a primary care team as evidenced from the recitation of "coordinating each said healthcare manager with at least one member of a primary care team." Similarly, claim 23 recites "coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are

followed by respective said patients." Thus, assigning healthcare managers to respective groups of patients, and using the healthcare manager to collect patient health-related data for each patient in his or her said group of patients (i.e., assigned group), is distinguished from Russek (i.e., the reference relied on in the final Office Action to purportedly teach the assigning step), which merely discloses that medical care providers such as doctors are assigned to patients. Further, col. 2, lines 33-35 and Figs. 11A-11D of Ballantyne were relied on in the final Office Action to purportedly teach the collecting step; however, Ballantyne merely teaches a medical care provider collecting patient data, and not a manager as claimed, as evidenced by the two "Administer Health Care" blocks 414 in Fig. 11B of Ballantyne.

4. Regarding claims 15 and 23, the Examiner states that the specification is silent on what exactly makes up a client plan of care (CPOC) and a medical plan of care (MPOC). Appellants disagree and respectfully direct attention to paragraph [0062] of the specification which states that the MPOC is at least initially set by the physician, by way of an exemplary embodiment. Paragraph [0065] and block 1220 in Fig. 4A of the specification illustrate that the CPOC is developed by the healthcare manager during an initial client visit. See also the "Manager" column in Fig. 7B of the specification that indicates that the "initial physician-set MPOC" are received via a conference with a physician (i.e., MD), and the "Extended Care Team" column in Fig. 7B that indicates that an MPOC is shared with the manager. See also the "Manager" column in Fig. 7C of

the specification which states that the manager "develops initial client plan of care." Claims 21 and 23 both recite that healthcare managers develop a CPOC during an interview with the patient, and the MPOC is developed using at least one member of the primary care team. As stated above, a healthcare manager is distinguished from a member of a primary care team as evidenced from the recitation of coordinating a healthcare manager with at least one member of a primary care team in claims 15 and 23. Appellants respectfully submit that the Examiner has improperly overlooked claim limitations recited in the independent claims and not set forth a complete basis for rejection under 35 U.S.C. § 103(a). For example, the Examiner fails to indicate what in Joao specifically teaches a CPOC and an MPOC as claimed. The language relied on in Joao is merely general statements such as a diagnosis is determined per col. 4, lines 33-39, and data from a list of participants in the healthcare field is incorporated into a comprehensive processing system per col. 12, lines 22-43. Joao, however, is silent regarding a CPOC developed during an interview of a healthcare manager with a patient, and an additional recited MPOC developed by the manager with a primary care team.

E. Claim 22 is Not Obvious under 35 U.S.C. § 103(a) over Ballantyne et al, Joao, Russek, Soll et al in view of Official Notice

Appellants respectfully submit the Examiner takes Official Notice of excluding a patient from a treatment program because he is a minor. Claim 22, however, also recites excluding a patient from a treatment program based on the criteria that the patient cannot communicate

effectively. No example or other statement was given by the Examiner of such an exclusion being old and notoriously well known.

F. Conclusion

For the reasons presented herein, Appellant submits that claims 1-25 are not rendered obvious under 35 U.S.C. § 103(a) by the cited references of record. Accordingly, reversal of the final rejection and allowance of claims 1-25 are respectfully requested.

Respectfully submitted,

Stacey Longanecker
Reg. No. 33,952

Roylance, Abrams, Berdo & Goodman, L.L.P.
1300 19th Street, N.W., Suite 600
Washington, D.C. 20036
(202) 659-9076

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